

## **XI. SUMMARY OF SAFETY AND EFFECTIVENESS**



### **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

#### **Medi-Vac Flexi-Clear™ Suction Handles**

**Manufacturer:** Allegiance Healthcare Corporation  
Productos Urologos de Mexico S.A. de C.V.  
Calle Norte Lote 1  
Parque Industrial III  
Mexicali-Baja Cal. Mexico 21210

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**Date Summary Prepared:** October, 1996

**Product Trade Name:** Medi-Vac Flexi-Clear™ Suction Handles

**Common Name:** Suction Handle

**Classification:** Tip, Suction, Rigid

**Predicate Devices:** Argyle® Yankauer Suction Tube

**Description:** The Medi-Vac Flexi-Clear™ Suction Handles are made of polyvinyl chloride in a variety of sizes and are offered sterile.

**Intended Use:** These suction handles are used in conjunction with a vacuum-powered, single patient, body fluid suction apparatus. The handles provide a means to aspirate, remove or sample body fluids from a surgical wound or body orifice via vacuum.

**Substantial Equivalence:** The Medi-Vac Flexi-Clear™ Suction Handles are substantially equivalent to Argyle® Yankauer Suction Tube in that they provide the following characteristics:

- intended use
- size, configuration, packaging
- made of polyvinyl chloride
- physical properties

**Summary of Testing:**

<u>Test</u>	<u>Result</u>
Cytotoxicity Test	Suction handle does not elicit any toxic reactions to acute application.
Intracutaneous Reactivity	No reactivity was observed.
Hemocompatibility	Suction handles are hemocompatible exhibiting no lysis.
Systemic Toxicity	Suction handle does not display potential for irritation.
Sensitization	Suction handle does not display any potential for irritation.